

Table 1: Obesity Pharmacotherapy Trials in Children and Adolescents

Study	Type of Study	Subjects	Treatment Duration	Non-drug Intervention	Study Groups	No of Subjects	Final Number of Subjects (% Completing Study)	BMI (kg/m ²) or %IBW or weight (kg) at Baseline	Change in Weight (kg) or BMI (kg/m ²) at Endpoint	% Reduction in Weight at Endpoint	Side Effects in treated subjects
Bacon and Lowrey, 1967 [Bacon, 1967 #3070]	RCT	71% F, 5-17y >97 th weight percentile	1 mo then cross-over to other treatment for 1 mo	1000-1200 kcal diet prescription	d,l fenfluramine 10-20 mg bid or tid placebo	10	5 (50%)	NR	-3.0 kg	NR	Weakness, dizziness, fainting, disorientation
Pedrinola et al, 1994 [Pedrinola, 1994 #3208]	Not clear if randomized but has placebo control group	55% F Brazilian children 11-17 y, 120-260% IBW	12 months	800-1000 kcal/d diet, instructed to increase activity. Visits q2 mo	d,l fenfluramine 30-60 mg bid placebo	90	68 (76%)	29 ± 5 kg/m ² (154±24%)	-5.1 kg/m ² *	NR	Drowsiness (18%), dry mouth, nausea, diarrhea
Malecka-Tendera et al 1996 [Malecka-Tendera, 1996 #3093]	Non-randomized untreated control group	71% F Polish children 16 ± 2y, unresponsive to outpatient program	6 weeks	Inpatient admission for 3 weeks 600kcal/d diet, outpatient for 3 weeks 600kcal/d diet	D,l fenfluramine 15 mg BID No medication	19	19 (100%)	31 ± 5 kg/m ² 85 ± 19 kg	-3.9 kg/m ²	NR	Dry mouth (58%), sleep disorders (21%)
Komorowski et al, 1982 [Komorowski, 1982 #3111]	RCT	43% F Polish children age 9-15y	8 weeks	Low calorie diet	Mazindol 1mg/d Placebo	8	8 (100%)	66 ± 10 kg	-5.7 ± 1.5 kg*	-11.7%*	NR
Golebiowska et al, 1981 [Golebiowska, 1981 #3109; Golebiowska, 1981 #3110]	Not clear if randomized but has placebo control group	44% F Polish children age 9-16y	8 weeks	2 week residential 1600-1800 kcal/d, with supervised activity, then outpatient	Mazindol 1mg/d Placebo	21	21 (100%)	71 kg	-5.4 kg*	-7.6%*	Palpitations (9.5%), dry mouth (33%), skin eruption (4.7%)
Rauh and Lipp, 1968 [Rauh, 1968 #3066]	RCT with last observation carried forward	100% F Tanner IV or V pubertal development age 10-19y	12 wks	None, visits q2 wks	Chlorphentermine 65mg/d Placebo	15	13 (93%)	95 kg	-6.7 kg**	NR	None
Von Spranger, 1965 [von Spranger, 1965 #3100]	Placebo Controlled, unclear if randomized	Children, 5-15y	1 month	Diet prescription, 1 visit	Phentermine 5-15 mg/d Placebo Diet alone	41	41 (100%)	23 kg	-3.5 ± 1.5 kg	NR	None
Lorber 1966 [Lorber, 1966 #3099]	RCT	62% F age 3-15y >120% of IBW	1 mo then crossover for 1 mo, then crossover for 1 mo	No snacks between meals, no sweets, to tinned fruits	Phentermine 15 mg/d Amphetamine resinate 12.5 mg/d placebo	84 total	80% total 24 22 22	NR	-3.4 kg -2.2 kg -2.1 kg	NR	Insomnia, irritability
Stewart et al 1970 [Stewart, 1970 #3068]	RCT with last observation carried forward	58%F age 5-16y >97 th percentile for weight	8 wks then crossover for 8 wks	1200 kcal/d diet prescription	Diethylpropion 75 mg qd Placebo	24	NR	NR	-2.1 kg*	NR	Head ache, abdominal pain, increased activity
Andelman et al 1967 [Andelman, 1967 #3069]	RCT	84% F age 12-18y >120% of IBW	11 wk	No snacks between meals	Diethylpropion 75 mg qd Placebo	51	37 (73%)	154%	-5.1 kg	-16.9%	Drowsiness, jitteriness, nervousness, insomnia, dry mouth, irritability, headache
Lustig et al 1999 [Lustig, 1999 #2198]	Open Label	56% F children 8-18y with hypo-thalamic obesity	6 mo	Dietary counseling	Octreotide 5 µk/kg/d + TID	9	8 (89%)	36 ± 2 kg/m ²	-4.8 ± 1.8 kg -2.0 ± 0.7 kg/m ²	-4.6%	Edema (11%) abdominal discomfort, flatulence, or loose stools (78%), increased thyroid hormone requirements (67%), gall bladder sludging (44%)
Lustig et al, 2001 [Lustig, 2001 #3207]	RCT	39% F children 10-18y hypo-thalamic obesity	6mo	NR	Octreotide 5-15 µk/kg/d + TID Placebo	9	NR	All subjects 99 ± 6 kg 36 ± 1.3 kg/m ²	+1.6 ± 0.6 kg ** -0.2 ± 0.2 kg/m ² +9.2 ± 1.5 kg +2.2 ± 0.5 kg/m ²	NR	Diarrhea (100%), glucose intolerance (22%), bile sludging/gallstones (44%)
Yanovski et al 2001 [Yanovski, 2001 #3426]	Open Label	50% F Black and White children 12-17y	3mo	Psycho-educational program: 12 weekly meetings 30% fat; 500 kcal/d deficit diet	orlistat 120 mg TID	20	17 (85%)	44 ± 12 kg/m ²	-2.9 ± 4.8 kg -1.4 ± 1.8 kg/m ²	-2.6%	Low vitamin D (3/20); oily stools(20/20)
Farooqi et al 1999 [Farooqi, 1999 #2196]	Open Label	100% F leptin deficient	12mo	None	Recombinant Leptin	1	1 (100%)	48 kg/m ²	-16.4 kg -10.1 kg/m ²	-17.4%	None
Lutjens and Smid 1977 [Lutjens, 1977 #3106]	Open Label	8-14y children	3mo	Diet prescription	Metformin 500mg TID Diet alone	9	9 (100%)	29 ± 4 kg/m ² 68 ± 19 kg	-10.9 ± 4.1 kg	-16 ± 6%**	None
Lustig et al 1999 [Lustig, 1999 #3107]	Open Label	100% F 1.3-17y	28 weeks	Diet prescription	Metformin 500 mg TID	8	8 (100%)	39 ± 2 kg/m ² 116 ± 9 kg	-1.2 ± 0.7 kg/m ²	-3.4±1.9%	None
Freemark and Bursey 2000 [Freemark, 2001 #3342]	RCT	56% F African Americans and Caucasians age 12-19y with fasting insulin >15 µU/mL and family history of type 2 DM	6 mo	None Reported	Metformin 500 BID Placebo	16	15 (94%)	*42 ± 4 kg/m ²	-0.5 kg/m ² *	-1.3%*	Intermittent nausea (6%), transient abdominal discomfort or diarrhea (19%) Exacerbation of migraine (6%)
Molnar et al [Molnar, 2000 #3212]	RCT	50% F 14-18y Caucasian	5 mo	30% fat, 500 kcal/d deficit diet seen every 2-4 weeks	Caffeine 100-200 mg TID + Ephedrine 10-20 mg TID Placebo	16	16 (100%)	36.5 ± 6.1 185% 105 ± 24 kg	-7.9 ± 6.0 kg*	-2.2±5.8%*	Nausea, insomnia, tremor, dizziness, palpitation

RCT: Randomized, double-blind, placebo-controlled trial; NR: not reported. For cross-over studies, results from first treatment period are reported.
* $p<0.05$; ** $p<0.01$ vs. control